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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/784,174	02/16/01	STEINER J	22903XA-T

HM22/0917

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EXAMINER	
COOK, R.	
ART UNIT	**PAPER NUMBER**
1614	6

DATE MAILED: 09/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/784,174	Steiner Et A

Examiner	Art Unit
Rebecca Cook	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *5, 6, and 8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *5, 6, and 8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

The drawings have been approved by the draftsman.

Applicants are requested to clarify the continuing data. The inventor's Declaration claims benefit to 08/869,426, while the continuing information in the specification does not.

Claims 5-6, 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for FKBP-type immunophilin compounds, does not reasonably provide enablement for compounds that are not FKBP-type immunophilins in a composition to treat alopecia or promote hair growth. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The summary of the invention on page 4 discloses that only compounds having an affinity for FKBP-type immunophilins are contemplated for the instant method. Amending the claims to recite this limitation will overcome this rejection.

Claims 5, 6, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in the claims for the recitations "a second hair revitalizing agent."

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA128:43577.

The reference discloses that the instant compound promotes hair growth.

The instant claims differ over the reference in reciting a composition combined with a second agent that promotes hair growth.

However, in the absence of a showing of unexpected results in Declaration form it would be obvious to one of ordinary skill in the art to combine two compounds, each of which promote hair growth, in a composition. One would be motivated by the desire to increase the amount of hair growth.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-6 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No.

09/781,427 and claims 5-6 and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-32 of copending Application No. 09/879,888. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious when the compound of '427 and '178 is an N-linked ketone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are requested to identify applications in which there are conflicting claims and eliminate such claims from all but one application in the absence of good and sufficient reason for their retention during pendency in more than one application. See CFR 1.78(b). Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Applicants are also requested to identify any related cases in which there might be double patenting.

Steiner, CA 126:272710; Blaschke et al, 1974, CA85:78405k; Nicolaou et al, Am. Chem. Soc., 1993; Nicolaou et al, Che. Eur. J.,1995; Shu et al, J. Labelled Comp. Radiopharm., 1996; Smith, et al, J. Am. Chem. Soc., 1995; Soai et al, J. Chem. Soc. 1982; Waldmann, Synlett, 1990; Waldmann, Liebigs Ann. Chem, 1991; and Wasserman et al, J. Org. Chem., 54(22), 1989 could not be considered. They were not received.

The foreign language references were considered to the extent of their English language abstracts or their formulas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Friday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200

September 11, 2001